IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

UNITED STATES OF AMERICA *ex rel.* **Brook Jackson,**	
Plaintiff,	**CASE NO. 1:21-CV-00008-MJT**
v.	**ORAL ARGUMENT REQUESTED**
VENTAVIA RESEARCH GROUP, LLC; PFIZER INC.; ICON PLC,	
Defendants.	

VENTAVIA RESEARCH GROUP, LLC'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO DISMISS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

INTRODUCTION

Relator's opposition leaves no doubt that this lawsuit is just an extension of her internet-driven anti-vaccine crusade. Though Relator claims to know better, the U.S. government—along with many others—extensively studied, approved, and encouraged the use of Pfizer's COVID-19 vaccine. The government continues to do so because it believes the vaccine saves lives. While Relator may have passionate personal opinions about the government's decision-making, her lawsuit fails to state any viable claim for relief under the False Claims Act. It should be dismissed.

That is true for several independent reasons that Ventavia raised in its motion to dismiss (Dkt. 53). As a threshold matter, Relator has not identified *any* false claims for government payment—the linchpin of any FCA case. In fact, she admits the only alleged claims for government payment in her Amended Complaint (Pfizer's invoices to DoD) "do not contain false statements." (Opp. 10.) Relator nevertheless argues those claims were "rendered" false by what she says were violations of the clinical trial protocol at two test sites out of hundreds. That accusation is wrong as a matter of fact and law, including because many of the alleged violations weren't violations at all—Relator either doesn't understand what she saw (because she worked for Ventavia for just 18 days and failed to complete all required training) or she doesn't want to understand.

But Relator is right about one thing: the Court need not get into those weeds to dismiss the case. Even if Ventavia did not perfectly comply with every aspect of the protocol in the midst of a global emergency, that's not enough to state an FCA claim. As the Supreme Court said in *Escobar*, the FCA is not a vehicle for policing regulatory violations (and Relator can't even show that). She tries to clear that gap by arguing Defendants falsely certified compliance with federal regulations, but that doesn't work either: because she hasn't identified any false certifications and because the government has said repeatedly any protocol violations were *immaterial* to its payment decisions.

To avoid repetition and to stay within page limits, Ventavia adopts and incorporates by reference the arguments addressed in Pfizer and Icon's reply briefs. Ventavia focuses below on two arguments especially relevant to the claims against it: Relator's failure to allege (1) causation under her indirect FCA theories, and (2) retaliation. Ventavia also addresses the Court's alternative authority to dismiss Relator's claims as a sanction for her willful breach of the FCA seal.

ARGUMENTS IN REPLY

I. Relator has failed to state a claim for FCA violations—including because Ventavia did not submit (or cause the submission of) any false claims.

As noted above, Relator's claims fail because she has not alleged any false claims for government payment as to any defendant, certainly not with the particularity required by Rule 9(b). (Dkt. 53 at 8-12.) In their reply briefs, Pfizer and Icon further address why Relator's opposition solves nothing on this essential element. Counts I and II should be dismissed for this reason alone.

Yet even if Relator could clear the false-claim hurdle, she has not sufficiently alleged that Ventavia itself violated the FCA—so at a minimum, the claims against it (and likely Icon as well) must be dismissed. Relator does not argue that these so-called subcontractors directly submitted any claims for government payment; so Relator effectively concedes she is asserting *indirect* FCA claims against them for allegedly causing the submission of Pfizer's false claims. (*See* Opp. 17.) In briefly attempting to support that theory, Relator generally argues that Defendants ("Respondents") made false certifications that, she says, caused the FDA to approve the Pfizer vaccine; and that, she says, ultimately led to DoD paying Pfizer's invoices. (*Id.*) These indirect claims fail for the reasons addressed by Pfizer and Icon, including because Relator has not plausibly alleged that any Defendant submitted any materially false certifications.[1]

[1] Relator's claims about Ventavia's "Form 1572" fail for the same reasons addressed in Icon's motion and reply brief, which Ventavia again incorporates by reference. Relator does not even

For present purposes, though, Relator's indirect FCA claims against Ventavia also fail because she cannot allege the necessary causal link between its actions and Pfizer's allegedly false claims. These indirect theories require Relator to show that Ventavia caused Pfizer to submit false claims or that it made or used false records or statements that caused the submission of false claims. (Dkt. 53 at 18-19, citing 31 U.S.C. § 3729(a)(1)(A)-(B); *see also* Dkt. 37 at 26 (explaining that some false claim is still required).) Proving causation requires a "sufficient nexus between [its] conduct and the ultimate presentation of the allegedly false claim," *i.e.*, an "affirmative act" that was a substantial factor in inducing Pfizer to submit claims for government payment. *United States ex rel. Colquitt v. Abbott Labs.*, No. 3:06-cv-01769, 2016 WL 80000, at *6 (N.D. Tex. Jan. 7, 2016); *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 714 (10th Cir. 2006). Relator does not contest this proximate-cause standard or Ventavia's supporting authorities. The only case she cites (from the Sixth Circuit) says nothing meaningful about causation; it just recites causation as an element without expanding on the relevant standard. (*See* Opp. 17.)

Nor does Relator argue or allege that Ventavia proximately caused Pfizer to submit false claims to the government. At best, she asserts in a conclusory fashion that the alleged conduct at Ventavia's trial sites caused the FDA to approve the Pfizer vaccine under false pretenses. (*Id.*) Even if that were accurate (it is not), Relator's theory is still one step removed from the alleged submission of false claims. Such a "generalized daisy chain of causation" does not meet the pleading requirements of Rule 9(b) or the legal requirements of the FCA. *See Sikkenga*, 472 F.3d at 728 n.34; *see also D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7-10 (1st Cir. 2016) (concluding relator could

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support her basic allegation that Ventavia submitted any such form to the government (Opp. 8-9), as her attached "representative example" is just a blank form. (Dkt. 17-1 at 55.)

not establish "causal link" between alleged misrepresentations to get FDA approval for medical device and the submission of claims to CMS by healthcare providers).

In fact, Relator all but concedes she *cannot* show a proximate link between Ventavia's trial sites and Pfizer's claims for government payment—because she relies exclusively on a chain of alleged "but for" connections. (*See* Opp. 17 (claiming "[b]ut-for the emergency use authorization, the government would have never paid Pfizer for the vaccines" and "but-for the favorable, albeit manipulated clinical trial data, an objective FDA would not have issued Pfizer the EUA").) First-year law students know that but-for causation is a low bar; and while it is a necessary component of proximate causation, it is not sufficient. *See Sikkenga*, 472 F.3d at 714 (rejecting "broad 'but for' test" under the FCA). Because Relator only discusses but-for causation in her opposition and does not go the next step to discuss proximate causation (much less plead the necessary facts), she has not cleared the causal gap for her indirect theories against Ventavia and Icon.

Relator has not even sufficiently alleged but-for causation. She admits that in approving Pfizer's vaccine, the FDA relied on data from roughly 44,000 Phase 3 trial participants. (Complaint ¶ 80.) She alleges Ventavia enrolled 1,500 of those participants (only 3%), though the real number (1,126) is lower than that. (Dkt. 53 at 16 n.6.) Whatever the precise percentage, Relator has not alleged that the data from the Ventavia participants was the deciding factor in the FDA's approval decision. (And the FDA has said the opposite, as discussed in Defendants' materiality arguments.) That means Relator has not alleged but-for causation. Relator claims the "FDA would not have an objective basis to determine the safety and efficacy of the vaccine" without Ventavia's so-called certifications (Opp. 17), but that argument fails as a matter of pleading (because it's not supported by anything) and basic logic (because the FDA had roughly 42,000 other data points to go on). In

other words, Relator has not sufficiently alleged that any false statements by Ventavia caused the FDA to issue the EUA (as she claims), and that's still at least a step removed from what Relator actually has to show (that Ventavia proximately caused Pfizer's claims for government payment).[2]

At a minimum, Relator has not alleged causation for her indirect FCA theories with the specificity required by Rule 9(b) or the plausibility required by Rule 12(b)(6). The Amended Complaint only generally alleges that Defendants "caused the presentment" of false claims (Complaint ¶¶ 274, 281) and made or used false records or statements to cause false claims to be paid (*id.* ¶ 284). These are precisely the kinds of formulaic and conclusory allegations that are prohibited by *Twombly* and *Iqbal*. *Sinclair v. Petco Animal Supplies Stores, Inc.*, 581 F. App'x 369, 371 (5th Cir. 2014). Relator also fails to give the particularized details necessary to satisfy Rule 9(b) for these indirect theories. (Dkt. 53 at 20-21 (citing authorities).) To the extent Relator tries to supply some detail now, she cannot amend her pleadings through a response brief (*e.g., Energy Coal S.P.A. v. CITGO Pet. Corp.*, 836 F.3d 457, 462 n.4 (5th Cir. 2016))—and she should not be granted leave to amend in any event, for reasons that Icon discusses in its reply. Ventavia respectfully submits that Counts I and II should be dismissed against it (and likely Icon), if nothing else.

II. Relator has failed to state a claim for FCA retaliation—including because she was not engaged in "protected activity" under the FCA.

Count III asserts a claim for FCA retaliation against Ventavia alone—because Relator did not work for anyone else—but it fails just as resoundingly as Counts I and II. That is because Relator cannot allege the most basic requirement of an FCA retaliation claim: that she was engaged in "protected activity" prior to her termination. (Dkt. 53 at 21.) Relator protests but does not

[2] To the extent Relator believes her misguided fraudulent-inducement theory clears this causal gap, she is also wrong for the reasons addressed in Pfizer's reply brief.

discuss any supporting allegations until the end of her argument, where she says she "repeatedly alerted Ventavia to violations of Pfizer's clinical trial protocol and FDA regulations." (Opp. 31.) That misses the point: any such complaints were not protected activity as a matter of settled Fifth Circuit law. And there is no need to resolve disputed facts to dismiss Count III on that basis.

Initially, much of Relator's retaliation argument is legally irrelevant because it relies on out-of-circuit authorities that may (or may not) impose a different standard for protected activity than the Fifth Circuit. (Opp. 28-29.) There is no need to go outside the Fifth Circuit because its caselaw is clear: for internal reports to be protected under the FCA, the relator must have raised concerns about false claims for government payment—not merely criticized the company's business practices. *United States ex rel. Patton v. Shaw Servs., L.L.C.*, 418 F. App'x 366, 372 (5th Cir. 2011). As the Fifth Circuit explained in drawing that distinction, "'an employer is entitled to treat a suggestion for improvement as what it purports to be rather than as a precursor to litigation.'" *Id.* (citing *Luckey v. Baxter Healthcare Corp.*, 183 F.3d 730 (7th Cir. 1999)). And, importantly, if an employer doesn't know the relator is concerned about fraud under the FCA, it "could not possess the retaliatory intent necessary to establish a violation of § 3730(h)." *Id.* (quotations omitted).[3]

Relator's allegations are on the wrong side of that line because, at best, she vaguely complained Ventavia was not strictly complying with the trial protocol and FDA regulations—but never suggested those alleged shortcomings resulted in false claims for government payment. Relator does not seem to understand that references to FDA regulations don't help her; as Defendants have addressed, the FCA is not a vehicle for policing regulatory compliance. *Universal*

[3] Under Fifth Circuit precedent, it is irrelevant whether relator "believed" there was fraud on the government, as Relator suggests. (Opp. 29.) The question is whether the relator *reported* it to her employer—because without such a report, there can be no retaliation as a matter of fact or law.

Health Servs., Inc. v. United States ex rel. Escobar, 579 U.S. 176, 194 (2016). Yet Relator doubles down by pointing to allegations where she says she "referenced FDA regulatory violations" and the possibility of an FDA warning letter. (Opp. 31; Complaint ¶¶ 33, 259.) That misses the point under the FCA. So does the alleged admission from a Ventavia representative that something might be a "problem" (Opp. 31); setting aside the fact that Relator butchers the context of the conversation, that was *not* an admission of a problem under the FCA—because no one was talking about (or thinking about) false claims for government payment. Relator does not come close to sufficiently alleging that she was engaged in FCA protected activity, so there was no retaliation.

Dismissal is required here for the same reasons the Fifth Circuit discussed in *Patton*, where the relator said he was fired because he "complained repeatedly" about "fraudulent construction mistakes." 418 F. App'x at 372. The Fifth Circuit found those reports were not protected activity because "the substance of his complaints" concerned allegedly unsafe or improper construction methods, not false claims for government payment. *See id.* The same is true here. Relator attempts to distinguish *Patton* by saying the relator there didn't reference any contractual provision or federal regulation. (Opp. 29.) Again, that's a meaningless distinction because the FCA is about false claims for government payment, not violations of contracts or regulations. Since the relator in *Patton* didn't raise that concern, he was not engaged in protected activity—just like the Relator here and just like the relator in *Robertson v. Bell Helicopter Textron, Inc.*, 32 F.3d 948, 951 (5th Cir. 1994) (finding no retaliation when employee raised concerns about government overcharges because he "never used the terms 'illegal,' 'unlawful,' or '*qui tam* action'").

To escape those authorities, Relator suggests the 2009 amendments to Section 3730(h) somehow changed the relevant standard for "protected activity." (Opp. 30.) They did nothing of

the sort. At best, the amendments clarified that a relator need not have already filed a lawsuit for her activity to be protected. But that has never been Ventavia's argument. The amendments *did not* alter the settled standard discussed above—that the relator must at least raise concerns about false claims for government payment. As a matter of text, the amended statute still only extends to efforts to stop "violations of this subchapter" (the FCA)—not mere regulatory violations. 31 U.S.C. § 3730(h). As Relator highlights, the Fifth Circuit in *Thomas* reinforced that fact when it addressed the amended statute, noting the protected activity must be "motivated by a concern regarding fraud against the government." *Thomas v. ITT Educ. Servs., Inc.*, 517 F. App'x 259, 262 (5th Cir. 2013). And Relator's primary authority (*Melchior v. Apple Homecare Med. Supply, Inc.*) does the same. No. 16-CV-1301-RP, 2018 WL 1876287, at *2-3 (W.D. Tex. Jan. 8, 2018) (noting employee must "clearly convey that the concerns focus on fraud against the federal government").

In this District, Judge Crone applied the amended language in 2019 and dismissed a retaliation claim using the same old standard, explaining that internal reports are protected only "if they raise concerns about fraud instead of merely criticizing the underlying subject." *United States ex rel. Reddell v. DynCorp Int'l, LLC*, No. 1:14-cv-86, 2019 WL 12875471, at *16 (E.D. Tex. Mar. 20, 2019). Tellingly, Relator does not mention *Reddell* in arguing the standard is now somehow different. It is not. Because Relator did not raise concerns about false claims under the FCA, she was not engaged in protected activity and Ventavia certainly did not know it.

Relator's alleged report to the FDA fails especially on that ground—she never alleges that Ventavia *knew* about that alleged communication (because it didn't). (Dkt. 53 at 23-24.) Relator simply says she called the FDA "[t]he same day" she was fired. (Opp. 31.) That is beside the point. Relator never alleged Ventavia knew about the phone call. And she doesn't argue otherwise here,

even after Ventavia challenged this point in its motion, except in a brief aside declaring—without support—that she was terminated for her reports of misconduct to the FDA. (Opp. 28.) That is logically impossible: Relator could not have been terminated for reports Ventavia didn't know about. So, as in *Patton*, 418 F. App'x at 372, even "assuming that [s]he contacted…authorities prior to [her] termination," Relator has not shown and cannot show that "'[her] complaints to the governmental entities were known to defendant'" (because they were not).

Relator has not stated a viable claim for FCA retaliation. Count III should be dismissed.

III. Although the Court need not dismiss Relator's claims as a sanction for her breach of the seal—because they fail on the merits—the Court has authority to do so.

Near the end of her response, Relator addresses an issue everyone agrees the Court need not reach: dismissal as a sanction for her willful violations of the FCA's sealing requirement. (Opp. 33.) There is no need to reach that argument because Relator's claims fail on the merits. And Ventavia believes a merits dismissal best serves the public interest. (Dkt. 53 at 24.) But, the Court unquestionably has discretionary authority to dismiss Relator's claims as a sanction. Ventavia will briefly address some of Relator's arguments to the contrary for the sake of completeness.

Relator primarily argues that dismissal is *never* appropriate for a seal breach where there is no harm to the government. (Opp. 34.) That's simply not correct, and it is not what the Supreme Court said in *Rigsby*: the court there held that the question of dismissal should be left to the district court's discretion, and it appeared to approve the consideration of multiple factors, including "the reputational harm FCA defendants may suffer when the seal requirement is violated." *See* 137 S. Ct. 436, 444 (2016). The Fifth Circuit considers: (1) the harm to the government, (2) the nature of the seal breach, and (3) the existence of willfulness or bad faith. (Dkt. 53 at 25.)

Most critically, Relator has no response to the evidence showing her seal breach was willful

and in bad faith. Relator disputes whether there was any seal breach at all (Opp. 33), but the judicially noticeable evidence shows she publicly posted the case caption on Twitter about a month before the case was unsealed along with allegations from the complaint. (Dkt. 40-1 at 87.) Relator breached the seal as a matter of undisputed fact. And she *does not* dispute or explain her own admissions of willfulness: that she knew she wasn't supposed to violate the seal but did it anyway because she was frustrated about being "silenced." (*See id.* at 6.) Just two weeks ago, Relator admitted on Twitter that she lost her first set of attorneys "[b]ecause I wanted to break the court ordered seal." https://tinyurl.com/4w52e5fr. It's hard to find clearer evidence of a willful breach.

Those and other comments illustrate that Relator's primary goal in this suit is to "bring[] information forward to the public," whatever the cost. (*See* Dkt. 40-1 at 6.) Shortly after the June 9, 2022 status conference, one of Relator's lawyers (Robert Barnes) went on a YouTube show, told viewers that the Court had ordered a status conference "in which he wanted to lecture me" about Relator's tweets, and declared that "I'm not gonna shut up." https://youtu.be/Qj5egZCcqZo. These continuing efforts to litigate the case on the internet further support a finding that Relator breached the seal in bad faith, thus activating the Court's dismissal authority. (*See* Dkt. 53 at 26.) To make matters worse, these public attacks threaten the Defendants' reputations in ways that are unjustified, inappropriate, and frankly unfair. That is why Ventavia would prefer dismissal on the merits: to make clear there hasn't been any FCA violation here. But short of that, Ventavia just wants this baseless lawsuit to be over. So, in the alternative—or perhaps even as an additional basis for dismissal—Ventavia submits that the Court may dismiss Relator's claims as a sanction.

CONCLUSION AND PRAYER

Ventavia respectfully requests the same relief requested in its Motion. (Dkt. 53 at 27.)

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document was served upon all counsel of record on September 20, 2022, pursuant to the Court's ECF filing system and the Federal Rules of Civil Procedure.

/s/ Taryn M. McDonald
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